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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,428	08/04/2006	Hiroshi Nagai	SHOBA6.001APC	9228

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EXAMINER

PERREIRA, MELISSA JEAN

ART UNIT	PAPER NUMBER
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1618

NOTIFICATION DATE	DELIVERY MODE
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10/14/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/588,428	Applicant(s) NAGAI ET AL.	
	Examiner MELISSA PERREIRA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1,2 and 5-7 are pending in the application. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

Response to Arguments

Affidavit/Declaration

1. The declaration under 37 CFR 1.132 filed 8/10/10 is insufficient to overcome the rejection of claims 1,2 and 5-7 based upon the rejection as set forth in the last Office action because: the preparations of the test beverages 1 and 2 are not identical as the test beverage 1 “Benifuuki” tea leaves are extracted at 90°C and the test beverage 2 “Yabukita” tea leaves are not extracted at 90°C but appear to be extracted at ambient temperature. Thus, the comparison between the two test beverages is not accurate and the unexpected results are not established.

2. Further, the reference of Zeyuan et al. teaches that black tea may be used to lower triglyceride levels and Suzuki et al. teaches that extracts of Benihomare comprise O-methylated catechin derivatives. The tea is extracted with hot water and not at ambient temperature. The declaration does not include a comparison of any black teas.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1,2 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeyuan et al. (*J. Agric. Food Chem.* **1998**, 46, 3875-3878) in view of Suzuki et al. (*J. Agric. Food Chem.* **2000**, 48, 5649-5653) and in further view of Iwasaki et al. (US 7,014,876B2) as stated in the office action mailed 3/11/10.

5. Applicant asserts that Zeyuan et al. does not indicate which substance in the extract has a BTG-reducing effect. Moreover, Tables 2 and 3 of Zeyuan et al. show that although the difference in catechin content between green tea and black tea is large, the difference in BTG reduction is small (BTG was decreased an average of 33.3% by green tea, and by 25% by black tea). In addition, Table 2 of Zeyuan et al. shows that although tea leaves contain a variety of catechins, it does not disclose or suggest any relationship between catechin type and BTG reduction effect. As such, Zeyuan teaches that the amount of catechins present in the tea is not correlated with the BTG-reducing effect. In view of this teaching, Zeyuan does not even suggest that any of the catechins within the green and black teas are responsible for their effect on reduction of BTG levels, much less that methyl catechins in particular have an unexpected effect.

6. The instant claims are not drawn to the method of reducing triglyceride levels in an individual by administering only the catechins of the instant claims but are drawn to the method of reducing triglyceride levels in an individual by administering a functional beverage which may comprise other constituents, such as methylated catechins.

7. Although the amount of catechins in the extract of Zeyuan et al. does not correlate with BTG reducing effects it would have been obvious to one skilled in the art

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that the black tea extract/functional beverage of Zeyuan et al. and its constituents, such as the catechins are used for the method of reducing triglyceride levels in an individual.

8. Suzuki et al. teaches that O-methylated catechin derivatives, such as (-)-epigallocatechin-3-O-(3-O-methyl) gallate (EGCG3"Me) are extracted from the tea leaves of Benihomare cultivar (black tea). Therefore, it would have been obvious to one skilled in the art that the EGCG3"Me of the black tea extract of Suzuki et al. may be used as a constituent of the black tea extracts/functional beverage of Zeyuan et al. for the method of reducing blood triglyceride levels.

9. Applicant asserts that Suzuki et al. does not teach that EGCG3"Me and EGCG4"Me have BTG reducing effects.

10. The reference of Suzuki et al. was not used to teach that EGCG3"Me and EGCG4"Me have BTG reducing effects but was used to teach that O-methylated catechin derivatives, such as (-)-epigallocatechin-3-O-(3-O-methyl) gallate (EGCG3"Me) are extracted, with hot water, from the tea leaves of Benihomare cultivar (black tea), etc. Therefore, it would have been obvious to one skilled in the art that the EGCG3"Me of Suzuki et al. may be used as a constituent of the black tea extracts/functional beverage of Zeyuan et al. and thus used for the method of reducing blood triglyceride levels.

11. Applicant asserts that Iwasaki et al. does not teach that BTG levels are reduced by consuming a beverage containing 5 mg to 30 mg/100 mL of methylated catechins according to the instant claim 1.

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12. Iwasaki et al. was not used to teach that BTG levels are reduced by consuming a beverage containing 5 mg to 30 mg/100 mL of methylated catechins but used to teach that catechins found in black tea are used in the healthy drink in an amount from 0.092 to 0.5 g per 100 ml and thus it is predictable to provide for a black tea containing catechins in an amount from 0.092 to 0.5 g per 100 ml in a healthy drink. Further, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.) to advantageously improve the function of the liver. It is noted that “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

13. Applicant asserts that although each of Zeyuan et al. and Iwasaki et al. disclose catechins extracted from tea leaves, the methylated catechins recited in the present claims are specific catechins which are present in large quantities in the specific tea leaves recited in the present claims and these methylated catechins differ from the catechins described in Zeyuan et al. and Iwasaki et al.

14. Zeyuan et al. and Iwasaki et al. teach of black tea extracts, not excluding those recited in the instant claims. Suzuki et al. teaches of black tea extracts of Benihomare cultivar comprising the O-methyl catechins of the instant claims and encompass the tea leaves of the instant claims and therefore have the same properties and are capable of

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the same functions, such as suppressing allergic rhinitis and effective for improving hyperlipidemia and gall bladder/liver functions.

15. Applicant asserts that nothing in the prior art would suggest to one having ordinary skill in the art to select the particular green teas recited in Applicants' claims. Applicants refer to the Maeda-Yamamoto et al. reference (Nippon Shokuhin Kagaku Kaishi 48:64-68, 2001), which was discussed in Applicants' response filed July 1, 2009. This reference teaches that strongly fermented teas, such as black tea, contain only trace levels of EGCG" 3Me. Nevertheless, black tea has a BTG reduction effect.

16. Maeda-Yamamoto et al. states that a higher concentration of EGCG3"Me was found on or after the second crop in Benihomare and Benifuji (abstract).

17. Suzuki et al. teaches that O-methylated catechin derivatives, such as (-)-epigallocatechin-3-O-(3-O-methyl) gallate (EGCG3"Me) are extracted from the tea leaves of Benihomare cultivar (black tea).

Conclusion

18. No claims are allowed at this time.

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618